IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
DAVID WILLIAMS, Plaintiff, vs. ENDO PHARMACEUTICALS, INC., and PROSTRAKAN GROUP, PLC, Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.: 1:15-cv-00695

Plaintiff, David Williams, through his undersigned counsel Burg Simpson Eldredge Hersh & Jardine, P.C., hereby alleges as follows:

INTRODUCTION

1. This case involves the prescription drug Fortesta, which is designed, manufactured, sold, distributed and promoted by and/or on behalf of Defendants Endo Pharmaceuticals, Inc. and ProStrakan Group, PLC. (hereinafter "Defendants") as a testosterone replacement therapy.

2. Defendants misrepresented that Fortesta is a safe and effective treatment for hypogonadism and/or what Defendants describe as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thromboembolic events.

3. Fortesta is an exogenous form of the androgen testosterone. It regulates the expression of platelet TXA_2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

4. Fortesta is delivered transdermally and is applied to the inner portion of the thighs in the form of a gel. Fortesta is made available in metered-dose canisters containing 60 grams of gel solution, which contains 10 mg of testosterone per 0.5 grams of gel, or a total of 1200 mg of testosterone. Each 60 gram canister provides a total of 120 pump actuations, which releases 10 mg of testosterone per pump actuation. The recommended starting dose is 40 mg of testosterone (4 pump actuations) applied once daily to the thighs in the morning. The dose can be adjusted between a minimum of 10 mg of testosterone and a maximum of 70 mg of testosterone per day.

5. Defendants failed to adequately warn physicians about the risks associated with the Fortesta and the monitoring required to ensure their patients' safety.

6. Defendants engaged in aggressive direct-to-consumer and physician marketing and advertising campaigns for Fortesta. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low testosterone" or "Low T," which was ultimately designed to over-promote and sell Fortesta.

7. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner."

Available at: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

8. The FDA has not approved any testosterone replacement therapy drug as a treatment for low testosterone or "Low T." Additionally, low testosterone is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

9. As a result of Defendants' "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially.

10. However, consumers of Fortesta and their physicians were misled by Defendants as to the drug's safety and efficacy, and as a result many consumers have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

PARTIES

Plaintiff David Williams

11. Plaintiff David Williams is a citizen of the United States of America, and is a resident of Ada County, Idaho.

12. Plaintiff David Williams began using the prescription drug Fortesta in or about December 2011 and continued using Fortesta as directed by his physician. On January 24, 2013, while using Fortesta, Plaintiff suffered and was diagnosed with a heart attack, specifically an acute inferior wall myocardial infarction. Plaintiff discontinued using Fortesta shortly after his heart attack. Plaintiff David Williams' heart attack was caused by his use of Fortesta.

13. At the time of Plaintiff David Williams' injuries at issue in this action, he was a resident of the State of Idaho.

Defendants Endo Pharmaceuticals, Inc. and ProStrakan Group, PLC

14. Defendant Endo Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business located at 1400 Atwater Drive, Malvern Pennsylvania, 19355.

15. Defendant Endo Pharmaceuticals, Inc. is an operating company of Endo International Plc, a global specialty healthcare company based in Ireland. Endo Pharmaceuticals, Inc. focuses on developing and delivering branded products in the United States, including but not limited to testosterone products, such as Aveed, Delatestryl, and Fortesta.

16. According to Fortesta's product labeling, Fortesta is actually manufactured for Endo Pharmaceuticals, Inc. by a German company Pharbil Waltrop GmbH. However, Endo Pharmaceuticals, Inc. assumes any and all liability that may be attributed to Pharbil Waltrop GmbH regarding the manufacturing and distribution of Fortesta in the United States.

17. Defendant ProStrakan Group, Plc is a United Kingdom based company with a place of business and representative in the United States located at 685 Route 202/206, Suite 101, Bridgewater, New Jersey 08807.

18. ProStrakan Group Plc is a specialty pharmaceutical company and is a subsidiary of Kyowa Hakko Krin Co. Ltd, a Japan-based global pharmaceutical company.

19. By way of background, ProStrakan Group, Plc originally developed the drug Fortesta. According to news reports, on August 26, 2009, Endo Pharmaceuticals announced that it had signed an agreement with ProStrakan Group Plc for the exclusive rights to commercialize Fortesta in the United States. At that time, Fortesta was in registration in the United States,

where ProStrakan's New Drug Application was under review by the U.S. Food and Drug Administration. Under the terms of the agreement, Endo Pharmaceuticals agreed to make an upfront payment to ProStrakan of $10 million, with the potential for up to $40 million more in milestone payments by the end of 2010 for FDA approval and the achievement of certain milestones. Endo Pharmaceuticals also agreed to pay ProStrakan an additional $160 million upon the achievement of certain sales targets. ProStrakan agreed to exclusively supply Fortesta to Endo Pharmaceuticals in the United States for an undisclosed supply price.

20. At all times herein mentioned, and at the time of Plaintiff's use of Fortesta, Defendants Endo Pharmaceuticals, Inc. and ProStrakan Group, Plc researched, developed, promoted, marketed, supplied, distributed, and sold to other distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public the pharmaceutical product Fortesta in this judicial district, in the State of Idaho, and in interstate commerce, and was the holder of the exclusive right to commercialize Fortesta in the United States of America.

JURISDICTION AND VENUE

21. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $75,000.00, exclusive of interest and costs.

22. Plaintiff is filing this Complaint directly in MDL No. 2545 by agreement of the Parties and as permitted by Case Management Order No. 12 issued by Judge Matthew F. Kennelly of this Court. Plaintiff states that but for CMO No. 12 allowing direct filing in MDL No. 2545, Plaintiff would have filed this action in the United States District Court for the District of Idaho, which is the venue in which Plaintiff resides.

23. Venue is proper in the United States District Court for District of Idaho pursuant to 28 U.S.C. § 1391(b)(2) and 1391(c)(2), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred within the District of Idaho, because the District of Idaho is the judicial district in which Plaintiff resides, and because Defendant is an entity who is subject to the personal jurisdiction of Idaho courts with respect to the civil action in question.

24. Therefore, Plaintiff respectfully requests that, at the time of remand and transfer of this action back to the trial court for further proceedings, this case be transferred to the United States District Court for the District of Idaho pursuant to Case Management Order No. 12.

FACTUAL BACKGROUND

General Allegations

25. This action is for damages brought on behalf of Plaintiff David Williams who was prescribed and supplied with, received and who has taken and applied, the prescription drug Fortesta, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff David Williams to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

26. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

27. At all times herein mentioned, Defendant was engaged in the business of, or was successor in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling,

inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Fortesta for the use and application by men, including, but not limited to, Plaintiff.

28. At all times herein mentioned, Defendants were authorized to do business within the state of residence of Plaintiff, within the state in which Plaintiff's injuries arose, and within the State of Illinois.

29. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

Regulatory History and Approved Uses

30. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

31. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

32. In men, testosterone levels normally begin a gradual decline after the age of thirty.

33. The average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dL on one day will have normal testosterone levels the next. Additionally,

testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease.

34. The Food and Drug Administration approved Fortesta on December 29, 2010 for the treatment of adult males who have low or no testosterone (a condition called Hypogonadism) in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy. After FDA approval, Fortesta was widely advertised and marketed by Defendants as a safe and effective testosterone replacement therapy.

35. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism occurs under the circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders and other conditions which cause suppression of gonadotropin-releasing hormone (GnRH).

36. In 1999, when Unimed Pharmaceuticals Inc., one of the original companies seeking FDA approval of testosterone replacement therapy drugs, asked for FDA approval of a similar drug AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men." The company represented to the FDA that it would market and sell the drug to this patient population of one million men who have an actual diagnosis of hypogonadism with associated medical condition. This was a false representation that the company made to the FDA in order to obtain approval of the drug. Defendants have adopted and continue to promote this false representation.

37. In 2000, the company announced that the market had increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

38. Additionally, a Canadian study showed that only about 6.3% of men who were prescribed testosterone actually met the diagnostic criteria for hypogonadism.

39. At all times material hereto, and since the time that Fortesta first received approval from the FDA, Defendants knew and understood the FDA-approved indications for clinical use of the Fortesta product.

Direct to Consumer Marketing and Promotion to Physicians for Unbranded/Off-Label Use

40. Defendants expanded the indications for use by promoting and detailing "Low T" as an acquired form of hypogonadism, and advantaged intentional ambiguity in the Fortesta product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

41. Although the FDA had previously told testosterone manufacturers that "claims and representation that suggest that AndroGel (and other testosterone therapy medications, such as Fortesta) is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading," and that testosterone replacement therapies were only approved for men with

hypogonadism, pharmaceutical companies, including Defendants, continued to market and promote testosterone replacement therapy for “andropause” and “Low T.”

42. Defendants coordinated a massive advertising campaign targeted toward men who did not have hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. The direct to consumer marketing was designed to convince men that they suffered from a non-existent and unrecognized medical condition called “Low T,” which was a term for low testosterone. Defendants orchestrated and/or participated in a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Fortesta users, and online media including the unbranded website "IsItLowT.com."

43. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

44. This national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to “take the ‘Is it Low T’ Quiz.” The “Is it Low T” quiz asks men if they have experienced potential signs of low testosterone, including, “Have you experienced a recent deterioration in your ability to play sports?”, “Are

you falling asleep after dinner?", "Are you sad and/or grumpy?", and "Do you have a lack of energy?"

45. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013 N.Y. TIMES.

46. Since the FDA approved Fortesta for a very specific medical condition called Hypogonadism, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

47. While running this disease awareness campaign, Defendants promote their product Fortesta as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

48. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for

years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

49. Defendants manufactured, sold and promoted the drug to treat a non-existent medical condition that it called "LowT," which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Defendants marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

50. As observed by Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. in their article "Low T as a Template: How to Sell Disease" published in JAMA Internal Medicine 173(15):1460-1462 (August 12/26, 2013) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a mass, uncontrolled experiment that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm.

51. Defendants' advertising paid off in an exponential increase of sales. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

52. Defendants' also engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T."

53. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States, and that the use of Fortesta is safe for human use as a treatment for "Low T," even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

54. At all times material hereto, Defendants' marketing strategy included the use of sales or drug detailing representatives ("Reps") and marketing and brand team personnel who performed on-line and in-person Fortesta product detailing to physicians; and also promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

55. Defendants' drug detailing "reps" provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the Fortesta product, as well as discount and/or rebate coupons to give to patients for the purchase of Fortesta.

56. Defendants' drug "reps" detailed and marketed Fortesta to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

57. Defendants denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

58. Defendants knew and understood the meaning of the terms "off-label" and "label expansion."

59. Defendants knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

60. Defendants marketed, promoted, and detailed Fortesta for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the Fortesta product.

61. A manufacturer or distributer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

62. A manufacturer or distributor misbrands a drug if the labeling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

63. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

64. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

65. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

66. The FDA did not, and never has, approved Fortesta for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or,

g. bone strength or density abnormalities.

Adverse Events and Serious Health Risks Caused by Testosterone Replacement Therapy ("TRT")

67. There have been a number of recent studies associating testosterone use in men with an increased risk of serious injuries from blood clots and cardiovascular events.

68. Testosterone replacement therapy involves the administration of exogenous testosterone into the male body in an attempt to raise the serum level of total testosterone. This is achieved through the application of a cream, gel or patch directly to the skin for transdermal absorption into the body. It can also be delivered into the body by subcutaneous injection or placement of a time-released pellet containing the drug.

69. The absorption of exogenous testosterone into the male body can cause an increase in serum levels of testosterone, and it also results in an increase in hematocrit[1] and serum estradiol levels.[2] It can also cause increased platelet aggregation and vasoconstriction.

70. Hematocrit is the proportion of total blood volume that is comprised of red blood cells. Erythrocytosis is an increase in the number of circulating red blood cells especially resulting from a known stimulus (like Testosterone). When a person's hematocrit level is raised through erythrocytosis, the resulting condition is called polycythemia, which simply means an elevated red blood cell count. The range for normal hematocrit levels in adult males is 44%-48%.

71. The administration of exogenous testosterone causes a 7%-10% increase in hematocrit levels in adult males through the process of erythrocytosis.[3] An increase of hematocrit that is 7%-10% above normal range is a significant elevation and qualifies as polycythemia. This is a serious medical condition that requires treatment to prevent injury.

72. The clinical trial data submitted to the FDA for the approval of testosterone replacement therapies showed that the use of exogenous testosterone resulted in nine percent of subjects experiencing hematocrit levels greater than 56% at some point during the study. A hematocrit level of 56% is significantly elevated above the normal range and qualifies as polycythemia. This is a level that puts the patient at serious risk for an adverse health consequence and requires immediate treatment and/or cessation of the testosterone therapy.

[1] Fernandez-Balsells, M., et al., Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. J Clin Endocrinol Metab, June 2010, 95(6):2560–2575.

[2] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[3] Bachman, E., et al. Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. J Gerontol A Biol Sci Med Sci., 2013.

73. Elevated hematocrit is an independent risk factor for stroke and it interacts synergistically with elevated blood pressure. In a published study[4] the cohort for men with a hematocrit level greater than or equal to 51% had a more than doubling of the risk of stroke (RR=2.5), and among males in the cohort who were also hypertensive there was a nine-fold increase in the risk of stroke for those with hematocrit greater than or equal to 51%.

74. Elevated hematocrit is also an independent risk factor for adverse cardiovascular events. Using data from the Framingham Heart Study, researchers documented a strong, graded relationship between hematocrit level and the risk of developing heart failure. In 3,523 Framingham participants, aged 50-65, who were free of a history of heart failure at baseline and were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had almost double the risk of new-onset heart failure during follow-up, compared with those with a low hematocrit, even after adjustment for conventional risk factors for heart failure.[5]

75. In another study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.[6]

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[4] Wannamethee G1, Perry IJ, Shaper AG, Hematocrit, hypertension and risk of stroke. J Intern Med. 1994 Feb;235(2):163-8.

[5] Coglianese, E., et al., Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. Am J Cardiol. Jan 15, 2012; 109(2): 241–245. Published online Oct 12, 2011

[6] Kunnas, T, et al., Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. Prev. Med. Volume 49, Issue 1, July 2009, Pages 45–47.

76. In yet another large, prospective study[7] in Norway, the data show a hazard ratio of 1.25 per 5% rise in hematocrit. In a category-based analysis, a hematocrit level in the upper 20th percentile was found to be associated with a 1.5-fold increased risk of venous thrombosis, and a 2.4-fold increased risk of unprovoked venous thromboembolism compared to men whose hematocrit was in the lower 40th percentile.

77. An increase in the level of hematocrit also causes an increase in the viscosity of the blood. A 10.99% increase of hematocrit produces an increase of 1 unit relative viscosity, which means approximately a 20% increase in blood viscosity for a healthy individual.[8] An increase in blood viscosity is a known risk factor for ischemic heart disease,[9] and it can cause hypertension as blood pressure increase will be 20% or vasodilation will be 4.66% in radius for the physiologic compensation of 20% increased viscosity. Hypertension is a known cause of atherosclerosis, heart failure, and stroke. Testosterone makes blood thick and viscous, which, in turn, can cause numerous health risks and injuries for patients.

78. The major source of estradiol in men comes from the aromatization of testosterone (endogenous and/or exogenous) to estradiol. When men are given testosterone, either by application of an androgen gel or by injection, some of that testosterone is converted by the body (aromatized) to estradiol.[10] The increase of estradiol is in direct

[7] Braekkan SK, Mathiesen EB,et al., Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. Haematologica. 2010 Feb; 95(2):270-5.

[8] Cinar, Y., et al., Effect of hematocrit on blood pressure via hyperviscosity. Am J Hypertens. 1999 Jul;12(7):739-43.

[9] Yarnell, JW, et al., Fibrinogen, viscosity, and white blood cell count are major risk factors for ischemic heart disease. The Caerphilly and Speedwell collaborative heart disease studies. Circulation. 1991 Mar;83(3):836-44.

[10] Glueck, CJ, et al., Thrombotic events after starting exogenous testosterone in men with previously undiagnosed familial thrombophilia. Trans. Res. Oct. 2011.

relation to the amount of the dose of exogenous testosterone delivered; the higher the dose of testosterone, the higher the level of serum estradiol.[11]

79. In data gathered from 2,197 men who participated in the Honolulu Aging Study from 1991-1993, and who were followed for thromboembolic and hemorrhagic events until 1998, there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower.[12] This study revealed that estradiol blood levels greater than 34.1 pg/mL resulted in this more than doubling of stroke incidence. As a source of embolism, the authors noted that the prevalence of atrial fibrillation rose significantly from 1.0 to 4.4% from the bottom to the top estradiol quintiles. Atrial fibrillation is a known cause of thrombus formation.

80. If men have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, then the estradiol can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones.[13]

81. In a study published in 2006, blood levels of estradiol were measured in 313 men whose average age was 58. Carotid artery intima-media thickness was measured at baseline and then three years later. After adjusting for other risk factors, men with higher levels of estradiol suffered a worsening thickening of their carotid artery wall. This led the researchers to conclude, "circulating estradiol is a predictor of progression of carotid artery intima-media thickness in

[11] Finkelstein, JS, et al., Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men. N Engl J Med 2013;369:1011-22.

[12] Abbott, RD, et al., Serum Estradiol and Risk of Stroke in Elderly Men. Neurology 2007, 68:563-568.

[13] Glueck, CJ, et al., Testosterone, thrombophilia, thrombosis. Blood Coagulation and Fibrinolysis 2014, 25:00–00.

middle-aged men."[14] These findings of a positive association between serum estradiol levels and intima-media thickening supports the notion that estrogens, besides possibly increasing the risk for thrombosis and thereby cardiovascular events, also have an important impact on atherogenesis (the formation of atheromas or plaque in the arterial walls) in men.

82. In a case control study of men in the Framingham cohort *supra*, serum estradiol levels were significantly increased in subjects with coronary heart disease.[15]

83. Estradiol has a greater effect in the male heart through the regulation of gene expression that it does not in female hearts. This effect results in impaired contractile function of the heart in males with elevated levels of serum estradiol. [16] Impaired contractile function results in numerous cardiovascular injuries and disease.

84. A study published in 2007 compared blood levels of testosterone and *estradiol* in men suffering acute myocardial infarction (heart attack) with those who had previously suffered a heart attack. Sex hormones were measured in patients presenting with acute heart attack, patients with old heart attack, and patients with normal coronary arteries. The results showed significantly higher levels of *estradiol* in both groups of heart attack patients compared with those without coronary disease.[17] In another study, men were admitted to the hospital with acute heart attacks whose levels of sex hormones were evaluated. Compared with control patients,

[14] Tivesten, A., et al., Circulating Estradiol is an Independent Predictor of Progression of Carotid Artery Intima-Media Thickness in Middle-Aged Men, J CLIN ENDOCRINOL METAB, November 2006, 91 (11): 4433-4437.

[15] Phillips GB, Castelli WP, Abbott RD, et al., Association of Hyperestrogenemia and Coronary Heart Disease in Men in the Framingham Cohort, Am J Med, 1983 74:863-869.

[16] Kararigas, G., et al., Transcriptome Characterization of Estrogen-Treated Human Myocardium Identifies Myosin Regulatory Light Chain Interacting Protein as a Sex-Specific Element Influencing Contractile Function, JACC Vol. 59, No. 4, January 24, 2012, 2012:410-7.

[17] Mohamad MJ, Mohammad MA, Karayyem M, Hairi A, Hader AA. Serum levels of sex hormones in men with acute myocardial infarction. Neuro Endocrinol Lett. 2007 Apr;28(2):182-6.

estradiol levels in these heart attack patients were **180%** higher, while bioavailable testosterone levels were **nearly three times less** than those of control patients.[18]

85. High testosterone levels also enhance acute myocardial inflammation, adversely affecting myocardial healing and early remodeling, as indicated by increased cardiac rupture, and possibly causing deterioration of cardiac function after myocardial infarction ("MI"), and, conversely, estrogen seems to have no significant protective effect in the acute phase after MI.[19]

86. Thromboxane A2 (TXA2) is a vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease. Thromboxane A2 has been unequivocally implicated in a range of cardiovascular diseases, owing to its acute and chronic effects in promoting platelet aggregation, vasoconstriction and proliferation. A study published in 1995 demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response and this effect may contribute to the thrombogenicity of androgenic steroids like testosterone.[20]

87. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

88. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels," in which a large cohort of men who used testosterone taken from a

[18] Pugh PJ, Channer KS, Parry H, Downes T, Jone TH. Bio-available testosterone levels fall acutely following myocardial infarction in men: association with fibrinolytic factors. Endocr Res. 2002 Aug;28(3):161-73.

[19] Maria A. Cavasin , Zhen-Yin Tao , Ai-Li Yu , Xiao-Ping Yang; American Journal of Physiology - Heart and Circulatory PhysiologyPublished 1 May 2006Vol. 290no. H2043-H2050DOI: 10.1152/ajpheart.01121.2005

[20] Ajayi, A., et al., Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. Circulation. 1995; 91: 2742-2747.

database of the Veteran's Administration was compared against a cohort of men who did not use testosterone. The data showed that among the cohort who used testosterone, the testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

89. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a comorbid condition. The conclusion of this published study was that the risk of myocardial infarction following initiation of testosterone therapy prescription is substantially increased.

90. In a study published in 2013[21], based on a systematic review and meta-analysis of placebo-controlled randomized trials of testosterone therapy among men lasting 12 or more weeks reporting cardiovascular-related events, two reviewers independently searched, selected and assessed study quality with differences resolved by consensus. Additionally, two statisticians independently abstracted and analyzed data, and concluded that testosterone therapy increased the risk of a cardiovascular-related event. Their meta-analysis of the published literature also showed that the effect of testosterone therapy varied with source of funding. In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone therapy was greater than in pharmaceutical industry funded trials. The study concluded that the existing body of published medical literature demonstrates that in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.

[21] Xu, L., et al., Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials. BMC Medicine 2013, 11:108.

91. In some patient populations, testosterone use can increase the incidence of adverse events and death by over 500%.

Inadequate Warnings and Labeling

92. Defendants' marketing strategy has been to aggressively market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of their products.

93. Defendants successfully marketed Fortesta by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low T."

94. Defendants' advertising program, sought to create the image and belief by consumers that the use of Fortesta was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

95. Defendants promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

96. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendants deceived potential Fortesta users and their physicians by relaying positive information through the press and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

97. Defendants concealed material relevant information from potential Fortesta users, and their physicians, and minimized user and prescriber concern regarding the safety of Fortesta, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

98. In particular, in the warnings Defendants provided in their commercials, online and print advertisements, Defendants failed to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represents that it adequately tested Fortesta for all likely side effects. Defendants also failed to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

99. At the time Plaintiff used Fortesta and suffered his injuries described herein, Fortesta's prescribing information and medication guide contained within the package materials did not warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

100. The medication guide contained within the package materials instructed patients to tell their healthcare provider whether they have any of the following conditions before initiating use of Fortesta:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

However, the prescribing information and medication guide contained within the package materials failed to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. They also failed to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease, which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

101. Although the prescribing information and medication guide contained within the package materials warned that the use of the product may result in increased red blood cell count, they did not instruct physicians or patients that the product can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count did not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor did it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals

with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

102. Although the prescribing information and medication guide contained within the package materials instructed physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, they failed to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also failed to instruct physicians to monitor their patient's hematocrit more frequently.

103. The prescribing information and medication guide contained within the package materials failed to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, such as the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant, because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones. They also fail to instruct physicians to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

104. Although the prescribing information and medication guide contained within the package materials warned that use of the product may result in risk of blood clots in the veins, they specifically limit this warning to "blood clots in the legs" and only warn against blood clots in the legs that form as a result of increased red blood cell count (polycythemia). There is no warning for blood clots in the veins other than "blood clots in the legs," nor is there any warning of blood clots resulting from causes other than polycythemia. Also, there are no warnings that blood clots in veins as a consequence of polycythemia could result in pulmonary embolism, or

other injuries secondary to the formation of deep vein thrombosis in the legs or other parts of the body.

105. The prescribing information and medication guide contained within the package materials failed to warn that use of the product may result in elevated levels of estradiol. They did not instruct physicians to monitor estradiol levels, nor did they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There was also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

106. The prescribing information and medication guide contained within the package materials did not warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

107. The prescribing information and medication guide contained within the package materials did not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There was no mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone replacement therapy, despite the fact that the data supporting this finding has been available for years. Instead, the label only stated that the manufacturer lacks any information regarding the safety or efficacy of testosterone therapy for men over the age of 65. This absence of a warning failed to

adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

108. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, et al. published as article in the Journal of the American Medical Association entitled Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels ("Vigen Paper").

109. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

110. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, et al. published an article in PLOS ONE entitled Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men ("Finkle Paper").

111. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

112. The increased incidence of heart attack and stroke was foreseeable at the time of the product launch of Fortesta.

113. Other studies and additional medical evidence, as described herein, indicate that the use of testosterone increases the risk of thromboembolic events, such as deep vein thrombosis ("DVT"), pulmonary embolism ("PE"), venous sinus thrombosis ("VST"), and other thrombotic events.

114. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the United States Food & Drug Administration ("FDA") announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism ("VTE"), including deep vein thrombosis ("DVT") and pulmonary embolism ("PE").

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

115. As a result of this mandate by the FDA, on June 21, 2014, Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE, and also updated the medication guide for Fortesta to include the significant risk of PE as follows: "Blood clots in the legs or lungs. Signs and symptoms of a blood clot in your leg can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain."

116. However, the prescribing information and the medication guide contained within the package materials still lacks any warning about the risks of elevated estradiol levels and the

need to screen for underlying clotting traits, and they contain no warnings for strokes, or for cardiovascular injuries.

117. The marketing and promotion of the product to patients and physicians overstated its benefits by creating the impression that it was a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

118. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Fortesta.

119. Had Plaintiff and his physician(s) known about the risks and dangers associated with Fortesta, as described herein, Plaintiff's physician would not have prescribed nor would Plaintiff have used Fortesta. Consequently, Plaintiff would not have been subject to its serious side effects, and/or Plaintiff's physicians would have adequately monitored Plaintiff's hematocrit and estradiol levels, and, as a result, Plaintiff's injuries would have not have occurred.

FACTUAL ALLEGATIONS SPECIFIC TO PLAINTIFF

120. Plaintiff David Williams was prescribed and began using Fortesta in December 2011. On January 24, 2013, while using Fortesta, Plaintiff David Williams suffered and was diagnosed with a heart attack, specifically an acute inferior wall myocardial infarction. He discontinued using Fortesta shortly thereafter.

121. Plaintiff was 50 years of age when he was prescribed and began using testosterone for symptoms he attributed to low testosterone. He was 51 at the time of his injury in January 2013.

122. As a direct and proximate result of using Fortesta, Plaintiff David Williams suffered the injuries described above.

123. Prior to and at the time of Plaintiff's use of Fortesta, Defendants knew or should have known that the use of Fortesta created a significantly increased risk of serious personal injury, including stroke, heart attack, blood clots, and even death, and that such use was unreasonably dangerous to consumers such as Plaintiff.

124. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Fortesta, Defendants failed to adequately warn Plaintiff David Williams and/or his health care providers of these risks before he used the product.

125. Had Defendants properly disclosed the risks associated with Fortesta and other testosterone products, Plaintiff David Williams would have avoided the risk of heart attack and other related injuries by either not using Fortesta and/or testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

126. As a direct and proximate result of Plaintiff's use of Fortesta, Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff David Williams suffered severe and permanent physical and emotional injuries, including, but not limited to a heart attack, which may have caused permanent effects, and may continue in the future to cause him physical effects and damages which will affect him throughout his lifetime.

127. Further, as a direct and proximate result of Plaintiff's use of Fortesta, Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff has suffered significant mental anguish and emotional distress

and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

128. Plaintiff David Williams has also suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future, as a direct and proximate result of his use of Fortesta and Defendants' conduct as described herein.

FIRST CAUSE OF ACTION

Strict Product Liability
Defective Manufacturing

129. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein and further alleges as follows.

130. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of the prescription drug Fortesta.

131. The Fortesta manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction, because it deviated from design or product specifications such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.

132. The Fortesta manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction as described herein at the time it left the Defendants' control.

133. As a direct and proximate result of Plaintiff's use of Fortesta as manufactured, designed, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff

suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SECOND CAUSE OF ACTION

Strict Product Liability
Design Defect

134. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein and further alleges as follows.

135. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Fortesta.

136. The Fortesta manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its design such that it was unreasonably dangerous, was not fit for the ordinary purpose for which it was intended, and/or did not meet the reasonable expectations of an ordinary consumer.

137. Specifically the Fortesta manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in its design because the product failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner and/or the risk of danger inherent in the design outweighed any alleged benefits associated with the product.

138. At the time Defendants manufactured, designed, distributed, sold, and/or supplied Fortesta into the stream of commerce, safer, more practical, alternative methods for treating alleged symptoms of "low testosterone" were available.

139. The Fortesta manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants was defective in design as described herein at the time it left Defendants' control.

140. As a direct and proximate result of Plaintiff's use of Fortesta as manufactured, designed, sold, supplied, and/or introduced into the stream of commerce by Defendants, and as a direct and proximate result of the defective nature of Defendants' Fortesta, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

THIRD CAUSE OF ACTION

Strict Product Liability
Defect Due to Inadequate Warnings or Instructions

141. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein and further alleges as follows.

142. The Fortesta manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions, because Defendants knew or should have known that the product was unreasonably dangerous to consumers in that it created a significant risk of serious bodily harm and death to reasonably foreseeable consumers, such as Plaintiff, and Defendants failed to adequately warn or instruct consumers and/or their health care providers of such risks.

143. The Fortesta manufactured and/or supplied by Defendants was also defective due to inadequate post-marketing warnings or instructions, because, after Defendants knew or should have known of the significant risk of serious bodily harm and death from the use of Fortesta, Defendants failed to provide adequate warnings to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

144. As a direct and proximate result of Plaintiff's reasonably anticipated use of Fortesta as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious personal injury, economic and non-economic damages, and will continue to suffer such harm, damages and losses in the future.

FOURTH CAUSE OF ACTION

Negligence

145. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein and further alleges as follows.

146. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Fortesta into the stream of commerce, including a duty to ensure that their product did not pose a significant increased risk of bodily harm and adverse events, such as stroke, heart attack, thromboembolism, and death, and a duty to adequately warn of the risks and dangers of Fortesta.

147. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion, and distribution of Fortesta into interstate commerce in that Defendants knew, or should have known, that the product caused such significant bodily harm or death and was not safe for use by consumers.

148. Defendants also failed to exercise reasonable care in the labeling of Fortesta and failed to provide to consumers and/or their health care providers adequate warnings of the increased risk of bodily injury or death due to the use of Fortesta.

149. Despite the fact that Defendants knew or should have known that Fortesta caused unreasonable, dangerous side effects, as described herein, Defendants continued to manufacture and market Fortesta for use by consumers including Plaintiff, even though there were safer alternative methods of treating loss of energy, loss of libido, erectile dysfunction, depression, loss of muscle mass, and other symptoms and conditions, which Defendants claims to be caused by low testosterone.

150. Defendants knew or should have known that consumers, such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

151. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty of Merchantability

152. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein and further alleges as follows.

153. At the time Defendants manufactured, marketed, sold, and distributed Fortesta, Defendants knew of the use of which Fortesta was intended and impliedly warranted to Plaintiff and to his physicians that Fortesta was of merchantable quality and safe for use as directed.

154. Plaintiff was and is unskilled in the research, design, and manufacture of Fortesta and reasonably relied on the skill, judgment and implied warranty of Defendants in deciding to use Fortesta.

155. Contrary to their implied warranty, Defendants' product Fortesta was not of merchantable quality or safe, because it was unreasonably dangerous as described herein.

156. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SIXTH CAUSE OF ACTION

Breach of Implied Warranty of Fitness for a Particular Purpose

157. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein and further alleges as follows.

158. At the time Defendants manufactured, marketed, sold, and distributed Fortesta, Defendants knew of the use of which Fortesta was intended and impliedly warranted to Plaintiff and to his physicians that Fortesta was fit for the particular purpose of treating men experiencing symptoms such as low energy, fatigue, and/or low libido, which Defendants identified as a condition known as low testosterone; rather than making it clear that Fortesta was only approved for treatment of men diagnosed with hypogonadism.

159. Plaintiff was and is unskilled in the research, design, and manufacture of Fortesta and reasonably relied on the skill, judgment and implied warranty of Defendants in deciding to use Fortesta.

160. Contrary to their implied warranty, Defendants' product Fortesta was not fit for the particular purpose of treating men experiencing symptoms such as low energy, fatigue, and/or low libido, because it was unreasonably dangerous as described herein.

161. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

162. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here and further alleges as follows.

163. Defendants expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Fortesta was safe, effective, fit and proper for its intended use.

164. Plaintiff purchased and used Fortesta, and Plaintiff's physician prescribed Fortesta, relying on the skill, judgment, representations, and express warranties of Defendants.

165. Contrary to Defendants' express warranties, Defendants' Fortesta did not conform to these express representations and warranties, because Fortesta caused serious injury to consumers such as Plaintiff who used the product when taken in the recommended dosages.

166. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

EIGHTH CAUSE OF ACTION

Fraud

167. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

168. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Fortesta, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Fortesta, which the Defendants had a duty to disclose.

169. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians

and the general public as to the benefits, health risks, and consequences of using Fortesta. Defendants knew that Fortesta is not safe, fit, or effective for human consumption, that using Fortesta is hazardous to health, and that Fortesta has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

170. Specifically, Defendants knew that Fortesta significantly increases the risk of thromboembolism, heart attack, stroke, and death, and that Fortesta is not safe and effective for treating men with symptoms such as fatigue, low energy, low libido, and other symptoms that are normal symptoms of aging in men.

171. Defendants concealed and suppressed the true facts concerning Fortesta with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe Fortesta, and Plaintiff would not have used Fortesta, if they were aware of the true facts concerning its dangers.

172. Defendants' fraudulent representations concerning the purpose for which Fortesta should be used and the safety of Fortesta were material representations.

173. Defendant knew its representations concerning both the purpose for which Fortesta should be used and the safety of Fortesta were false.

174. Nevertheless, Defendants made such representations to Plaintiff and his physicians with the intent to defraud Plaintiff and his physicians and with the intent of inducing their reliance upon such false representations.

175. Plaintiff and his physicians justifiably relied on Defendants' material representations to Plaintiff's detriment.

176. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

NINTH CAUSE OF ACTION

Negligent Misrepresentation

177. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein and further alleges as follows.

178. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Fortesta, and, while engaged in the course of such business, made representations to Plaintiff and his physicians regarding the character and/or quality of Fortesta for guidance in their decision to select Fortesta for Plaintiff's use.

179. From the time Fortesta was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Fortesta was safe, fit and effective for human consumption.

180. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

181. Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

182. The representations by the Defendants were in fact false, in that Fortesta is not safe, fit and effective for human consumption, using Fortesta is hazardous to health, and Fortesta has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

183. Defendants' representations were made negligently and/or with the intention of inducing reliance and the prescription, purchase, and use of Fortesta.

184. In reliance on Defendants' misrepresentations, Plaintiff was induced to purchase and use Fortesta. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Fortesta. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

185. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. For all causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue applicable in this case;

2. Awarding compensatory damages in excess of the jurisdictional minimum of this Court to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff, medical expenses, health care costs, and medical monitoring, together with interest and costs as provided by law;

3. Awarding all applicable statutory damages of the state whose laws govern this action;

4. Awarding Plaintiff reasonable attorneys' fees;

5. Awarding Plaintiff the costs of these proceedings;

6. Plaintiff reserves the right to amend his complaint to allege punitive damages under Idaho law; and

7. For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: January 23, 2015

Respectfully submitted,

/s/ Calvin S. Tregre, Jr.

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